



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Trauma Informed Care

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Trauma Informed Care*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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ATTN: EPC SEADs Coordinator

5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Trauma Informed Care*. AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Trauma Informed Care*. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/trauma-informed-care/protocol>

This is to notify the public that the EPC Program would find the following information on *Trauma Informed Care* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
 - *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements, if relevant: study*

number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this topic.*

In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

TIC for Adult Patients/Clients

- KQ 1. What is the evidence of benefits and/or harms of TIC on outcomes for patients/clients?
 - KQ 1a. Which components (e.g., education and training of providers about trauma, screening patients, delivering point-of-care interventions [note this is not meant to include established evidence-based treatments for trauma-related disorders], referring patients/clients for various forms of additional assessment and treatment for indicated needs) of TIC models, and organizational and practice characteristics, are associated with benefits and/or harms?
 - KQ 1b. Do outcomes vary by patient/client or clinical or organizational characteristics, including the nature, extent and timing of exposure (e.g., recent or ongoing vs. prior exposure in childhood)?

TIC for Child and Adolescent Patients/Clients

- KQ 2. What is the evidence of benefits and/or harms of TIC on outcomes for patients/clients?
 - KQ 2a. Which components (e.g., education and training of providers about trauma, screening patients, delivering point-of-care interventions [note this is not meant to include indicated evidence-based treatments for trauma-related disorders], referring clients for various forms of additional assessment and treatment for indicated needs) of TIC models, organizational and practice characteristics, are associated with benefits and/or harms?
 - KQ 2b. Do outcomes vary by patient/client (as well as parent) or clinical or organizational characteristics including the nature, extent, and timing of exposure (e.g., recent or ongoing vs. prior exposure)?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

PICOTS	KQ1	KQ2
Population	<p>Adults 18 years and older, regardless of trauma exposure</p> <p>1b. Patient/client and clinical characteristics including type, time since, and duration of trauma exposure; gender; race/ethnicity; age; clinical condition; or disorder (e.g., anxiety, depression, substance use)</p>	<p>Youth <18 years, regardless of trauma exposure</p> <p>2b. Patient/client and clinical characteristics including type, time since, and duration of trauma exposure; gender; race/ethnicity; age; clinical condition; or disorder, (e.g., anxiety, depression, ADHD, conduct disorder, substance use)</p>

PICOTS	KQ1	KQ2
Intervention	<p>TIC models/components of care (e.g., education and training of providers about trauma, screening patients/clients for trauma exposure using ACEs or other tools, screening for symptoms, delivering point-of-care interventions, referring patients/clients for various forms of additional assessment and treatment for indicated needs)</p> <p>1a. single or multi-component, individual or group, targeting organizations, providers, patients/clients, caregivers, or a combination, training, screening</p>	<p>TIC models/components of care (e.g., education and training of providers about trauma, screening patients/clients for trauma exposure using ACEs or other tools, screening for symptoms, delivering point of care interventions, referring patients/clients for various forms of additional assessment and treatment for indicated needs)</p> <p>2a. single or multi-component, individual or group, targeting organizations, providers, patients/clients, caregivers, or a combination, training, screening</p>
Comparator	<p>No TIC model of care/usual or routine care (CAU)</p> <p>Other TIC model or component(s) of care, evidence-based therapies for trauma-related conditions (e.g., prolonged exposure, cognitive processing therapy) or approaches (e.g., Collaborative Care)</p>	<p>No TIC model of care/usual or routine care (CAU)</p> <p>Other TIC model or component(s) of care, evidence-based therapies for trauma-related conditions (e.g., trauma-focused CBT) or approaches (e.g., Collaborative Care)</p>
Outcome	<p><i>Trauma-Specific:</i> Additional or repeat trauma exposure from the point-of-care in the course of care/service delivery (e.g., retraumatization)</p> <p><i>Process outcomes:</i> Health care outcomes/utilization/referral, provider burnout/mental health</p> <p><i>Organizational/ practice/ systems outcomes:</i> Intake and referral processes (e.g., wait times), disseminated policies, trainings, staffing (e.g., scribes), administrative requirements, access to treatment, workforce diversity</p> <p><i>Patient/client-centered outcomes:</i> Physical and mental health outcomes, functioning, clinical improvement, patient/client engagement, trust, comfort or satisfaction, and strengths-based outcomes (e.g., quality of life)</p> <p><i>Harms:</i> Includes displacement of evidence based care (e.g., screening for anxiety, depression, substance use, suicide risk), increase in patient/client aggression or other behavioral misconduct.</p>	<p><i>Trauma-Specific:</i> Additional or repeat trauma exposure from the point-of-care in the course of care/service delivery (e.g., retraumatization)</p> <p><i>Process outcomes:</i> Healthcare outcomes/utilization/referral, provider outcomes burnout/mental health</p> <p><i>Organizational/ practice/ systems outcomes:</i> Intake and referral processes (e.g., wait times), disseminated policies, trainings, staffing (e.g., scribes), administrative requirements, access to treatment, workforce diversity, anti-racism principles</p> <p><i>Patient/client-centered outcomes:</i> Physical and mental health outcomes, functioning, clinical improvement, patient/client engagement, trust, comfort or satisfaction, and strengths-based outcomes (e.g., quality of life)</p> <p><i>Harms:</i> Includes displacement of evidence based care (e.g., screening for developmental milestones, ADHD, depression, anxiety, suicide risk, substance use), increase in patient/client aggression or other behavioral misconduct.</p>
Timing	Any	Any
Setting	Routine or emergency healthcare in any setting that provides human or social services, including in nontraditional settings (e.g., HIV clinics providing behavioral health care)	Routine or emergency healthcare in any setting that provides human or social services, including in nontraditional settings (e.g., school-based clinics providing behavioral health care)

Dated: October 27, 2023.

Marquita Cullom,

Associate Director.

